Nanotechnology and Regulatory Science in FDA

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Outline

Overview of regulatory science activities in FDA

1. **Current activities**
2. **Key challenges**
3. **Future directions**

FDA Nanotechnology Regulatory Science Activities

I. Agency and Center-level

II. Interactions with domestic stakeholders

III. International Interactions

IV. Regulatory Science Initiative

FDA Activities

I. Agency and Center-level

1. Nanotechnology Task Force
2. Intramural research programs
3. Nanotechnology Regulatory Science Plan
4. Agency- and Center-level policy documents
5. Ongoing review of products

FDA Activities (cont'd)

II. Interactions with domestic stakeholders

1. USG partnerships
   - National Nanotechnology Initiative
   - WH Emerging Technologies- Inter-Agency Policy Coordination
2. Ongoing interactions with US regulatory agencies
   - EPA
   - CPSC
   - NIEHS
3. Collaboration
   - Universities
   - NIH, NCI-NCL
   - NIST
4. Public meetings
   - 2006 with industry, consumers, other stakeholders
   - 2008 Public Meeting
   - CDRH public workshop in 2010

FDA Activities (cont.)

III. International Interactions

1. Ongoing communication with international regulatory agencies (EU, UK, Japan, Australia, Canada)
2. Participation in standards-setting bodies
   - ISO TC 229
   - ASTM

FDA Activities (cont.)

IV. Regulatory Science Initiative

1- Initiate CORES (*Collaborative Opportunities for Research Excellence*) Program

2- Enhance Laboratory capacity to assess nanotechnology products and their safety

3- Promote staff development and training

Key challenges for development and deployment of nano-based products

- Evolving state of science - - Mechanistic understanding and test methods
- Risk management challenges in case-by-case evaluation
- Current regulations are flexible so as to incorporate new emerging fields such as nanotechnology
- Guidance documents are continuing to evolve

Guidance Documents

- FDA

  - Draft guidance published for comments

  http://www.fda.gov/ScienceResearch/SpecialTopics/Nanotechnology/ucm257926.htm

- CDER

  - Drugs containing nanomaterials are like any new drug.

  - Many published Guidance documents,

  -- are applicable and

  -- may be used by sponsors.

- CDRH

  - In preparation

Gaps remain in developing test methods and standards

- Identification and assessment of nanoscale materials in products

- characterization methods

- biocompatibility and toxicity assessment

Future directions

Implementation of 2011 FDA Nanotechnology Regulatory Science Program

1- Initiate CORES (*Collaborative Opportunities for Research Excellence*) Program

2- Enhance Laboratory capacity to assess nanotechnology products and their safety

3- Promote staff development and training

Collaborative Opportunities for Research Excellence in Science (CORES)

Objectives

- **Support for research projects in nanotechnology regulatory science priority areas**
- **Emphasis on inter-agency projects**
  - **Enhanced coordination through NNI**
  - **CPSC, EPA, NIH, NIST, NSF, DARPA**
- **Support for joint FDA-Academia projects**
  - **Enhanced safety, toxicity programs**
  - **Development of internal FDA research priorities**

FDA 2011Nanotechnology Initiative- Examples of Current Regulatory Research Areas

1. Physico-Chemical Characterization in FDA-Regulated Products

- Improved methods and tools to detect and measure the physical structure, chemical properties, and safety of nanomaterials in FDA-regulated products:

2. Nonclinical Modeling of Nanomaterials in FDA-Regulated Products

- Develop and evaluate in vitro and in vivo assays and models to assess safety and/or efficacy of nanomaterials in FDA-regulated products, in order to:

3. Risk Characterization Information

- Enhance the understanding of hazard identification, exposure science, and risk modeling

4. Risk Assessment

- Enhance state of knowledge and scientific evidence to support potential development of generalized class-based approaches to risk assessment

(http://www.fda.gov/ScienceResearch/SpecialTopics/Nanotechnology/ucm196697.htm)

Summary

- **FDA mission**

  - Protecting public health and **fostering innovation**

- **Evolving science continues to address gaps:**

  - Identification and assessment of nanoscale materials in products

  - characterization methods

  - biocompatibility and toxicity assessment

More information available at FDA Websites

http://www.fda.gov/ScienceResearch/SpecialTopics/Nanotechnology/default.htm
http://www.fda.gov/Training/CDRHLearn/default.htm
Overview of Regulatory Requirements: Medical Devices
- Quality System Regulation 21 CFR Part 820 Basic Introduction
- Device Establishment Registration and Listing
- Overview of the Premarket Notification Process – 510(k)
- Bioresearch Monitoring (BIMO)

http://www.fda.gov/cdrh/devadvice/
http://www.fda.gov/cder/drug/default.htm
Investigational New Drug Application (21 CFR Part 312)
Applications for FDA Approval of a Biologic License (21 CFR Part 601
http://www.fda.gov/ScienceResearchSpecialTopics/Nanotechnology/default.htm

Measurements and Standards

Reference Value Mean Size and Expanded Uncertainty (a)
Average Particle Size (Diameter), in nm

Technique	Analyte Form	Particle Size (nm)
Atomic Force Microscopy	dry, deposited on substrate	8.5 ± 0.3
Scanning Electron Microscopy	dry, deposited on substrate	9.9 ± 0.1
Transmission Electron Microscopy	dry, deposited on substrate	8.9 ± 0.1
Differential Mobility Analysis	dry, aerosol	11.3 ± 0.1
Dynamic Light Scattering	liquid suspension	13.5 ± 0.1
Small-Angle X-ray Scattering	liquid suspension	9.1 ± 1.8